K123636 Summary
NESS H200® Wireless Hand Rehabilitation System
with optional Intelli-Connect Earpiece Triggering Device

Company name	Bioness Inc.
Contact	Kim Tompkins VP of Regulatory and Clinical Affairs Bioness, Inc. 25103 Rye Canyon Loop, Valencia, CA 91355 USA Office phone: (661) 362-5968 Fax: (661) 362-6661 Email: Kim.Tompkins@bioness.com
Date prepared	April 23, 2013
Trade name	NESS H200® Wireless Hand Rehabilitation System with optional Intelli-connect, trade name subject to change
Classification name	External functional neuromuscular stimulator
Class	II
Panel identification	Neurology
Product code	GZI and IPF
Regulation number	882.5810 External functional neuromuscular stimulators 890.5850 Powered muscle stimulators
Predicate device	NESS H200 Wireless Hand Device K111767

Purpose: This is a product line extension to add an optional hands-free trigger for functional stimulation of the H200 Wireless System.

Device description
The NESS H200 System consists of the following components:

- Functional Stimulation (FS) Orthosis with a Radio Frequency (RF) Stim Unit
- Control Unit
- Intelli-Connect triggering device optional accessory, consisting of an earpiece, a charger and connecting cable

The Intelli-Connect Earpiece triggering device is fitted over the ear and detects clicks of the teeth to wirelessly trigger the stimulation unit of the H200 Wireless orthosis. Software built into the Intelli-Connect earpiece is designed to register and work exclusively with the patient's orthosis. The Earpiece is rechargeable with a lithium-polymer battery. It is FCC identified and meets part 15 of the FCC regulations. Once the earpiece is turned on, Intelli-Connect will trigger stimulation when teeth are clicked together.

Indications for use

The NESS H200® Wireless Hand Rehabilitation System is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES):

- Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury

NeuroMuscular Electrical Stimulation (NMES):

- Maintenance and/or increase of range of motion
- Prevention and/or retardation of disuse atrophy
- Increase of local blood circulation
- Reduction of muscle spasm
- Muscle re-education

The Intelli-Connect is an optional accessory device used exclusively with the H200 Wireless System. The Intelli-Connect is used to trigger the H200 Wireless Orthosis through simple jaw movements.

Substantial Equivalence

The H200 Wireless System is identical to the previously cleared system. The optional Intelli-Connect triggering device detailed in this submission was designed for use in the same target population. This accessory allows potentially more independence in the target population by allowing patients to turn on/off their H200 functional stimulation unit unassisted—contributing to more independence. A comparison of the predicate and subject triggering follows:

	H200 Wireless handheld triggering device K111767 (Predicate)	**H200 Wireless with Intelli-Connect (Subject)**
Effect of the trigger detection	Triggering the pre-determined stimulation sequence at the H200W orthosis	Same
Communication with the H200W orthosis	Wireless, using proprietary RF communication protocol	Same
Registration to the H200W system	Wireless, using proprietary RF communication protocol	Same
Power source	Rechargeable battery	Same
Trigger event	Pressing button on the control unit with the unaffected hand	Detecting vibrations associated with tooth clicking without using a hand

Performance Testing Summary

Purpose	Testing	Results
Verify that the Intelli-Connect complies with 60601-1 general requirements for basic safety and essential performance	Power input, leakage current, dielectric strength, mechanical strength, physical stability, excessive temperature, humidity, ingress of liquids, cleaning, mechanical abuse, stress relief	Pass
Verify that Intelli-Connect system complies with EMC requirements of 60601-1-2	Radiated emissions, AC mains, electrostatic discharge, immunity to surge, RF field immunity, magnetic field immunity, interruptions immunity	Pass
Verify that the battery satisfies IEC 62133:2202	Vibration, temperature cycling, external short circuit, free fall, crash hazard	Pass
Verify conformance with FCC Part 15 Class B	Field strength, bandwidth, spurious emissions, AC mains emissions, antenna requirement,	Pass
Verify conformance to biocompatibility (ISO 10993) requirements	Sensitization, cytotoxicity, irritation	Pass
Verify software meets requirements	Hardware verification, module verification, internal peripherals, settings, accelerometers, initialization, watch dog timer, charging, battery capacity, registration, LED behavior, state machine, trigger commands	Pass
Verify user specifications are met	Weight, charge access, insertion, donning and doffing, handling, talking, with glasses, consistent detection, roll and pitch, fit, cleaning	Pass

Conclusion

The H200 Wireless System with optional Intelli-Connect does not raise any new questions of safety and effectiveness and therefore is substantially equivalent to the cleared H200 Wireless System (K111767 SE 9.15.11).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 01, 2013

Bioness, Inc.
% Kim Tompkins
25103 Rye Canyon Loop
Valencia, CA 91355

Re: K123636
Trade/Device Name: NESS H200 Wireless Hand Rehabilitation System with optional Intelli-Connect Earpiece Triggering Device
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: March 15, 2013
Received: March 22, 2013

Dear Ms. Tompkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to: http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to:
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address:
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A

Indications for Use

510(k) Number (if known): K123636

Device Name: Bioness H200 Wireless Hand Rehabilitation System with

Indications for Use:

The [NESS] H200 Wireless System is an electrical stimulation device indicated for the following uses:

- Functional Electrical Stimulation (FES).
  - Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.
- NeuroMuscular Electrical Stimulation (NMES).
  - Maintenance and/or increase of hand range of motion.
  - Prevention and/or retardation of disuse atrophy.
  - Increase in local blood circulation.
  - Reduction of muscle spasm.
  - Re-education of muscles.

The Intelli-Connect is an optional accessory device used exclusively with the H200 Wireless Orthosis through simple jaw movements.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

Division of Neurological and
Physical Medicine Devices
510(k) Number: K123636